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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,479

06/28/2006

Izumi Kubo

1774-0118PUS1

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EXAMINER

DINH, BACH T

ART UNIT

PAPER NUMBER

1795

NOTIFICATION DATE

DELIVERY MODE

09/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/549,479	Applicant(s) KUBO ET AL.	
	Examiner BACH T. DINH	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial office action for application 10/549,479 filed on 06/28/2006.
2. Claims 1-8 are currently pending and have been fully considered.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Joko et al. (JP 2001264284) with machine translation.

Addressing claims 1-2, Joko discloses an electrode (figure 1), comprising:

An electrode base (electrode layer 3 on insulating substrate 2),

A self-assembled monolayer of HS(CH₂)₆COOH (4) covering the electrode base,

and

An enzyme (7) is immobilized on the self-assembled monolayer [0013].

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monbouquette (US 6,241,863) in view of Joko et al. (JP 2001264284).

Addressing claims 3-4 and 6, Monbouquette discloses a sensor comprising:

A vessel receiving a sample solution in which an object to be measured dissolves (5:8-21, the electrodes are disposed within an encasement of the electrochemical cell; 20:41-43, samples are injected into the electrochemical cell; therefore, the encasement of the electrochemical cell is the vessel), and

A modified electrode (figure 1) and a counter electrode (20:30-43, platinum counter electrode) to be dipped into the sample solution,

Wherein the modified electrode comprises:

An electrode base (figure 1, gold base layer), and

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A self-assembled monolayer expressed by a chemical structural formula of $S(CH_2)_3COO^-$ (9:32-50), with longer alkanethiols are preferred, which expresses the desire that the hydrocarbon chain $(CH_2)_n$ with n that is larger than 3 and covering the electrode base (figure 1),

An enzyme is immobilized on the self-assembled monolayer (figure 1, 9:4-15). Monbouquette further discloses a mediator is added into the sample solution (3:28-32). Monbouquette is silent regarding the self-assembled monolayer that has the chemical structural formula as required by current claim.

Joko discloses an electrode (figure 1), comprising:

An electrode base (electrode layer 3 on insulating substrate 2),

A self-assembled monolayer of $HS(CH_2)_6COOH$ (4) covering the electrode base, and

An enzyme (7) is immobilized on the self-assembled monolayer [0013].

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the electrode of Monbouquette with the self-assembled monolayer of $HS(CH_2)_6COOH$ as disclosed by Joko because the self-assembled monolayer of Joko is the alkanethiol compound with longer chain that is required by Monbouquette (Joko, figure 1; Monbouquette, 9:32-50). Furthermore, the self-assembled monolayer of Joko would prevent intramolecular branching reaction between the molecules of the enzyme and the intermolecular interaction arises in the thiol molecule (Joko, [0011]).

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Addressing claim 7, current claim recites a voltage applying means and a calculation means, which invoke 35 U.S.C. 112, sixth paragraph. According to the originally filed specification and drawings, the voltage applying means is the potentiostat 7 and the calculation means is the computer 9 (figure 1).

In 20:20-43, Monbouquette discloses the electrochemical cell is interfaced with a potentiostat or the claimed voltage applying means and a Macintosh computer or the claimed calculation means. The potentiostat and the computer of Monbouquette are the equivalent structures of the claimed voltage applying means and calculation means, respectively, for they perform the same function as the potentiostat and the computer of current application.

Addressing claim 8, Monbouquette discloses an Ag/AgCl reference electrode and the voltage applying means applies a predetermined voltage on the basis of a voltage the reference electrode to the modified electrode (20:38-43).

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monbouquette (US 6,241,863) in view of Joko et al. (JP 2001264284) as applied to claims 3-4 and 6-8 above, and further in view of Watanabe et al. (*Electrochemistry*, 2002, 70, 258-263).

Addressing claim 5, Monbouquette discloses the electrochemical sensor is used for measuring fructose (19:47-67).

Monbouquette is silent regarding the mediator is hydrophobic.

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Watanabe discloses a biosensor with the modified gold electrode for detecting fructose; wherein, phenanthroline cobalt complex is used as the mediator (Abstract, page 259 column 1).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the electrochemical sensor of Monbouquette with the redox mediator of Watanabe because the redox mediator of Watanabe would lower the working potential of the electrochemical sensor and avoid the influence of interferences (column 2 of page 258 to column 1 of page 259).

10. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (*Electrochemistry*, 2002, 70, 258-263) in view of Joko et al. (JP 2001264284).

Addressing claims 3-6, Watanabe discloses a sensor comprising:

A vessel (glass vial, see section 2.1) receiving a sample solution in which an object (fructose) to be measured dissolves, and

A modified electrode and a counter electrode to be dipped into the sample solution (section 2.2, modified gold electrode and platinum counter electrode),

Wherein the modified electrode comprises:

An electrode base (figure 1),

A self-assembled monolayer of glutaraldehyde covering the electrode base (figure 1), and

An enzyme (FDH) is immobilized on the self-assembled monolayer (figure 1).

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Watanabe further discloses phenanthroline cobalt complex is used as the mediator (Abstract, page 259 column 1).

Watanabe is silent regarding the SAM is expressed by the chemical formula $\text{HS}(\text{CH}_2)_n\text{COOH}$.

Joko discloses a modified electrode; wherein, the enzyme 7 is immobilized onto the gold electrode base layer via a SAM of $\text{HS}(\text{CH}_2)_6\text{COOH}$ (4, figure 1).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the sensor of Watanabe with the SAM layer of Joko because the SAM layer of Joko would provide many advantages over the SAM layer of glutaraldehyde (Joko, [0005-0008]) as well as preventing intramolecular-branching reaction between the molecules of the enzyme and the intermolecular reaction in the thiol molecule (Joko, [0001]).

11. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (*Electrochemistry*, 2002, 70, 258-263) in view of Joko et al. (JP 2001264284) as applied to claims 3-6 above, and further in view of Monbouquette (US 6,241,863).

Claim 7 recites a voltage applying means and a calculation means, which invoke 35 U.S.C. 112, sixth paragraph. According to the originally filed specification and drawings, the voltage applying means is the potentiostat 7 and the calculation means is the computer 9 (figure 1).

Addressing claims 7-8, Watanabe discloses an Ag/AgCl reference electrode (section 2.2) and the voltage is applied at a predetermined level on the basis of a voltage of the

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reference electrode to the modified electrode (section 3.5, the calibration curve in figure 7 is obtained at 0.3V vs. the Ag/AgCl electrode). Watanabe discloses voltage is applied in the same manner as required by current claims and the measured current is correlated to the concentration of fructose (figure 7).

Watanabe is silent regarding a voltage applying means and a calculation means.

Monbouquette discloses a sensor comprising a modified electrode (figure 1) for monitoring the concentration of biological molecules. The electrodes of the sensor are interfaced with a potentiostat or the claimed voltage applying means and a Macintosh computer or the claimed calculation means. The potentiostat and the computer of Monbouquette are the equivalent structures of the claimed voltage applying means and calculation means, respectively, for they perform the same function as the potentiostat and the computer of current application.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the sensor of Watanabe with the potentiostat and the computer of Monbouquette because the potentiostat would allow one to apply a predetermined voltage on the basis of a voltage of the reference electrode to the modified electrode and the computer would allow one to calculate the concentration of the analyte (Monbouquette, 20:38-43).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M-3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

BD
08/27/2009